



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,761	09/04/2003	Dennis Ausiello	17509-0065	6913
29052	7590	07/03/2006	EXAMINER	
SUTHERLAND ASBILL & BRENNAN LLP			HAN, MARK K	
999 PEACHTREE STREET, N.E.			ART UNIT	
ATLANTA, GA 30309			PAPER NUMBER	

3767

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/654,761	AUSIELLO ET AL.	
	Examiner	Art Unit	
	Mark K. Han	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21, 24, 27, 28, 30-33 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10, 12-21, 24, 27, 28, 32 and 34-36 is/are allowed.
- 6) ☒ Claim(s) 11, 30, 31, 33 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. <u>20060623</u>                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. The indicated allowability of claim 11, 30, 31, 33 and 37 is withdrawn in view of the newly discovered reference(s) to U.S. Patent No. 6,740,333 to Beckett et al. Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 11, 30, 31, 33 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,740,333 to Beckett et al. (hereinafter "Beckett").

In reference to claim 11, Beckett discloses a method for controlled deliver of parathyroid hormone to a female patient by inserting the medical device into the vagina, where the medical device has a substrate, a plurality of discrete reservoirs in the substrate and a release system containing parathyroid hormone. This system allows for the controlled release of a pharmaceutically effective amount of the parathyroid hormone from the reservoirs. See col. 4, lines 45-49; col. 10, line 57 through col. 11, line 2; col. 15, lines 28-39; col. 18, line 62 and col. 19, lines 44-48.

Art Unit: 3767

In reference to claims 30, 31, 33 and 37, Beckett discloses a method for controlled delivery of parathyroid hormone that includes varying the substrate material and/or concentration of the hormone so that proper dosage can be achieved. See Figures 2a and 2b. See also col. 31, lines 19-42; col. 34, lines 43-47 and col. 38, lines 49-52.

***Allowable Subject Matter***

4. Claims 1-10, 12-21, 24, 27, 28, 32 and 34-36 are allowed.

5. The following is a statement of reasons for the indication of allowable subject matter:

The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the implantable device having a plurality of discrete reservoir caps separating the release system from the outside environment and a means for disintegrating one or more reservoir caps by electrothermal ablation (claims 1 and 12); an electrically conduct reservoir cap covering each reservoir, conducting leads to and from each reservoir cap and a controller for selectively delivering an electric current through the reservoir cap effective to rupture the reservoir cap (claim 34, see also Remarks dated 06 June 2006, p. 2, lines 17-21 and p. 3, lines 7-13) in combination with the other elements (or steps) in the claims. Allowable subject matter for independent claim 28 was indicated in the Office Action mailed 16 November 2005.

***Contact Information***

Art Unit: 3767

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark K. Han  
Patent Examiner  
Art Unit 3767

mkh  
June 23, 2006

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

  
6/26/06